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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,846	01/17/2002	David Myatt Parker	C70334D1	3355

7590

07/29/2003

GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939

EXAMINER
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KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/051,846

Applicant(s)

PARKER, DAVID MYATT

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13, 22, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 22, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/485,898.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application***

Receipt is acknowledged of applicant's filing of Response on April 13, 2003. Claims 1 to 13, 22, 26 and 27 are currently pending for prosecution on the merits.

Acknowledgment is made of applicant's filing of the instant application as a divisional of USSN 09/485,898 on January 17, 2002 which after November 29, 2009. The Examiner likes thank Applicant to point out the application of the AIPA to the present filing.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-13, 22, 26 and 27 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is meant by "the sweet is a pastille". It appears in view the instant specification that the claimed composition may contain sweetner and can be formulated into candies, tablets, lozenges, chews, lollies, etc... Does applicant mean "the claimed composition can be prepared in the form of a pastille"?

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13, 22, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeWille et al. (US 5597595) or Burkes et al. (US 5445837).

DeWille teaches or suggests a powdered beverage concentrate comprising calcium compound (i.e., calcium glycerophosphate), an acid (i.e., citric acid, lactic acid, ascorbic acid) and sweetner (Tables 18-21; Example 7; Claims). As specific embodiments of the invention, examples Tables 18-21 disclose Ca: acid molar ratio = 0.66 (with ascorbic acid) or 0.68 (without ascorbic acid)--- [Ca moles = 39.67; Acid moles (88% lactic acid+ citric acid+ ascorbic acid)=59.7; Ca: acid molar ratio= 39.67/59.7=0.66] or [Ca moles=39.67; Acid moles (88% lactic acid+ citric acid)=39.67/58=0.68] and Example 7 discloses calcium to acid molar ratios is 0.71 (with ascorbic acid) or 0.74 (without ascorbic acid)---[Ca moles= 1.39; Acid moles (60% lactic acid+ citric acid + ascorbic acid)=1.94; Ca: acid molar ratio=1.39/1.94= 0.71 ] or [Ca

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moles=1.39; Acid moles (60% lactic acid+citric acid)= 1.89; Ca:acid molar ratio= $1.39/1.89=0.74$ ]. The reference also teaches or suggests that the pH of liquid beverage concentrate (prepared by mixing water with a powered beverage concentrate) is in the range of about 2.8 to 4.6.

Burke teaches or suggests a dry sweetener supplement composition comprising calcium compound and the acidulant (i.e., citric acid and malic acid), wherein the molar ratio of calcium to acid is about 0.8. The reference also teaches or suggests the effective pH of said composition less than equal to about 3.8 (column 9, lines 39-44), wherein pH is about 3.7 in dry powder form (column 12, lines 32-34).

The teaching of DeWille or Burke differs from the claimed invention (i) in the specific molar ratio of the calcium to acid, namely in the range of 0.3 to 0.65 (claim 1), more specifically at least 0.4 (claim 4), in the range of 0.3-0.6 (claim 26), in the range of 0.3-0.55 (claim 27); and (ii) "the sweet is a pastille" (claim 10). However, optimization of amounts of known active and inactive ingredients in a composition or the determination of optimum dosage form is well considered within the skill of the artisan, absent evidence showing why the particular range or dosage form is critical, generally by showing that the claimed range or dosage form achieves unexpected results relative to the prior art range.

Especially in light of ingredients used in disclosed herein, those of ordinary skill in the art would be able to arrive at the claimed range regardless of the criticality of the claimed molar ratio of the calcium to acid. For example, DeWille'595 teaches the use of 60% lactic acid or 88% lactic acid in formulating beverage composition. Those of ordinary skill in the art would have expected that said beverage concentrate could be prepared with either 60% or 88% lactic acid,

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and that Example 7 could be formulated with 88% lactic acid. When 88% lactic acid is used in Example 7, the molar ratio of the calcium to acid is 0.56 ( $1.39 / (1.21 + 1.76)$ ) which lies inside the claimed range. Therefore, regardless of the criticality of the claimed molar ratio of the calcium to acid, one having ordinary skill in the art would be able to formulate the claimed composition without undue experimentation.

Furthermore, since the instant specification defines that the term effective pH means the pH of the composition before solidification (where the composition is prepared via a liquid phase intermediate) or the pH of the composition when reconstituted or dissolved in a liquid, e.g., water (page 2, lines 26-29), the referenced pH of liquid beverage concentrate which is prepared by mixing water with the powered beverage concentrate having the claimed calcium to acid molar ratio in Example 7 “meets and bounds” the claimed limitation of “the effective pH of the solid or semi-solid composition is from 3.5 to 4.5.”

### Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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Brian Kwon

**ZOHREH FAY**  
**PRIMARY EXAMINER**  
**GROUP 1600**

A handwritten signature in cursive script, appearing to read 'Zohreh Fay', written in black ink.